



Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/660,112
		Filing Date	September 10, 2003
		First Named Inventor	Luskey, Kenneth L.
		Art Unit	1614
		Examiner Name	Cook, Rebecca
		Attorney Docket Number	016325-003721US
Sheet	1	of	6

U.S. PATENT DOCUMENTS+

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
M	23	CA	967,978		05-1975	Hazen		<input type="checkbox"/>
M	24	FR	1,476,525		04-1967	Balhofeur		<input type="checkbox"/>
M	25	GB	1,182,008		02-1970	Roberts, Jr.		<input type="checkbox"/>
M	26	WO	92/17435		10-1992	Boehringer Mannheim GmbH		<input type="checkbox"/>

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **Applicant's unique citation designation number (optional).** **Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 801.04.** Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). **For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.** **Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.** **Applicant is to place a check mark here if English language Translation is attached.**

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		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
W	27	GB	1,403,309		08-20-1975	Merck & Co. Inc.		<input type="checkbox"/>
	28	WO	00/74666	A2	12-14-2000	Metabolex, Inc. et al.		<input type="checkbox"/>
	29	WO	02/44113	A2	06-06-2002	Metabolex, Inc.		<input type="checkbox"/>
	30	WO	04/112774	A1	12-29-2004	Metabolex, Inc.		<input type="checkbox"/>

Examiner Signature	<i>R Cook</i>	Date Considered	<i>6/22/05</i>
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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/382,186 10/660112
(use as many sheets as necessary)				Filing Date	March 4, 2003
				First Named Inventor	Luskey, Kenneth L.
				Art Unit	1614
				Examiner Name	Cook, Rebecca
Sheet	3	of	6	Attorney Docket Number	016325-003740US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
✓	31	ARONOW, W.S. et al., "Halofenate: An Effective Hypolipemia- and Hypouricemia-Inducing Drug," <i>Current Therapeutic Research</i> , 15:902-906 (1973)		T ²
✓	32	ARONOW, W.S. et al., <i>Clin. Pharmacol. Ther.</i> , 14:371-373 (1973)		
	33	BARDIN, C.W., eds., CURRENT THERAPY IN ENDOCRINOLOGY AND METABOLISM, 6th Edition, Mosby - Year Book, Inc., St. Louis, MO (1997)		
✓	34	BARRETT-CÖNNOR, "Epidemiology, Obesity, and Non-Insulin-Dependent Diabetes Mellitus," <i>Epidemiologic Review</i> , 11:172-181 (1989)		
✓	35	BASSETT, D.R. et al., "Effects of halofenate and probenecid in serum lipids and uric acid in hyperlipidemic, hyperuricemic adults," <i>Clin. Pharmacol. Ther.</i> , 22:340-351 (1977)		
✓	36	BELL et al., "Glucokinase Mutations, Insulin Secretion, and Diabetes Mellitus," <i>Annu. Rev. Physiol.</i> , 58:171-186 (1996)		
✓	37	BERKOW and FLETCHER, "The Merck Manual of Diagnosis and Therapy - 15th Edition," pp 1069-1072, Merck Research Laboratories, N.J. (1987)		
✓	38	BLUESTONE, R. et al., <i>Arthritis Rheum.</i> , 18:859-862 (1975)		
✓	39	CHIASSON, J. et al., "The Efficacy of Acarbose in the Treatment of Patients with Non-Insulin-dependent Diabetes Mellitus," <i>Ann. Intern. Med.</i> , 121:928-935 (1994)		
✓	40	CONIFF and KROL, "Acarbose: A Review of US Clinical Experience," <i>Clinical Therapeutics</i> , 19:16-26 (1997)		
✓	41	CONIFF, et al., "Multicenter, Placebo-Controlled Trial Comparing Acarbose (BAY g 5421) With Placebo, Tolbutamide, and Tolbutamide-Plus-Acarbose in Non-Insulin-Dependent Diabetes Mellitus," <i>The American Journal of Medicine</i> , 98:443-451 (1995)		
✓	42	EDELMAN and HENRY, "Non-Insulin-Dependent Diabetes Mellitus," <i>Current Therapy in Endocrinology and Metabolism</i> , pp. 430-438 (1997)		
✓	43	FAJANS et al., "Maturity Onset Diabetes of the Young (MODY)," <i>Diabetes Medicine</i> , 13:S90-S95 (1996)		
	44	FANELLI, G.M., Jr., <i>J. Pharmacol. Exp. Ther.</i>, 180:377-396 (1972)		
✓	45	FELDMAN, E.B., et al. "Effects of Halofenate on Glucose Tolerance in Patients with Hyperlipoproteinemia," <i>Journal Clinical Pharmacology</i> , 18:241-248 (1978) May-June 1978		
✓	46	FELDMAN, E.B., et al. "Insulin Sensitivity in Hypertriglyceridemia: induction by combined triglyceride and uric lowering", <i>Clinical Research</i> vo. 23, No. 1, page 43A (1975)		

Examiner Signature	<i>Mlooh</i>	Date Considered	<i>01/22/05</i>
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				Examiner Name	Cook, Rebecca
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T ²					
JK	47	FLIER, "Insulin Receptors and Insulin Resistance," <i>Ann. Rev. Med.</i> , 34:145-160 (1983)			
JK	48	FRIEDBERG, "The Control of Insulin Resistant and Refractory Type II Diabetes Mellitus by Means of Halofenate-Sulfonylurea Combined Regimen," <i>Clinical Research</i> , 34:682A (1986)			
JK	49	GAVIN III et al., "Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus," <i>Diabetes Care</i> , 22:S5-S19 (1999)			
JK	50	GOETZE, et al., "PPAR γ -Ligands Inhibit Migration Mediated by Multiple Chemoattractants in Vascular Smooth Muscle Cells," <i>Journal of Cardiovascular Pharmacology</i> , 33:798-806 (1999)			
JK	51	HOWARD et al., "Lipoprotein Composition in Diabetes Mellitus," <i>Atherosclerosis</i> , 30:153-162 (1978)			
JK	52	HUCKER et al., "Metabolism of a New Hypolipidemic Agent, 2-Acetamidoethyl (<i>p</i> -Chlorophenyl) (<i>m</i> -Trifluoromethylphenoxy)-Acetate (Halofenate) in the Rat, Dog, Rhesus Monkey and Man," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 179:359-371 (1971)			
JK	53	HUTCHISON and WILKINSON, "The Uricosuric Action of Halofenate (MK-185) in Patients with Hyperuricemia or Uncomplicated Primary Gout and Hyperlipidemia," <i>Atherosclerosis</i> , 18:353-362 (1973)			
JK	54	IWAMOTO et al., "Effect of Combination Therapy of Troglitazone and Sulphonylureas in Patients with Type 2 Diabetes Who Were Poorly Controlled by Sulphonylurea Therapy Alone," <i>Diabetic Medicine</i> , 13:365-370 (1996)			
JK	55	JAIN, A. et al., <i>Clin. Pharmacol. Ther.</i> , 11:551-557 (1970)			
JK	56	JOSLIN, "Arteriosclerosis and Diabetes," <i>Annals of Clinical Medicine</i> , 5:1061-1079 (1927)			
JK	57	KELLER C. et al., <i>Arzneimittelforschung</i> , 28:2349-2352 (1976)			
JK	58	KUNTZNEN O. et al., <i>Arzneimittelforschung</i> , 28:2349-2352 (1978)			
JK	59	KNOWLER et al., "Obesity in the Pima Indians: Its magnitude and relationship with diabetes," <i>Am J Clin Nutr</i> , 53:1543S-1551S (1991)			
JK	60	KOHL et al., "Improved Control of Non-insulin-dependent Diabetes Mellitus by Combined Halofenate and Chlorpropamide Therapy," <i>Diabetes Care</i> , 7:19-24 (1984)			
JK	61	KREISBERG, R.A., "Hyperlipidemia," <i>Curr. Therapy Endocrin. Metabol.</i> , 6th Ed., pp. 509-519; Mosby-Yearbook, Inc. (1997)			
JK	62	KUDZMA and FRIEDBERG, "Potentiation of Hypoglycemic Effect of Chlorpropamide and Phenformin by Halofenate," <i>Diabetes</i> , 26(4):291-295 (1977)			
JK	63	KWITEROVICH, Jr., "State-of-the-Art Update and Review: Clinical Trials of Lipid-Lowering Agents," <i>The American Journal of Cardiology</i> , 82:3U-17U (1998)			

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<i>W</i>	64	LeROTH, D. et al. (eds.), <i>Diabetes Mellitus</i> , Lippincott-Raven Publishers, Philadelphia, PA U.S.A. (1996)			<i>T²</i>
<i>W</i>	65	LIN and LU, "Inhibition and Induction of Cytochrome P450 and the Clinical Implications, <i>Clin Pharmacokinet</i> , 35:361-390 (1998)			
<i>W</i>	66	MAHLER and ADLER, "Clinical Review 102, Type 2 Diabetes Mellitus: Update on Diagnosis, Pathophysiology, and Treatment," <i>The Journal of Clinical Endocrinology & Metabolism</i> , 84:1165-1171 (1999)			
<i>W</i>	67	MAHLEY et al., "Disorders of Lipid Metabolism," <i>Williams Textbook of Endocrinology</i> , 1099-1153 (1998)			
	68	McMAHON, F.G. et al., "Some Effects of MK-185 on Lipid and Uric Acid Metabolism in Man", <i>Univ. Mich. Med. Center J.</i> , 36(4):247-248 (1970)			
<i>W</i>	69	MINERS and BIRKETT, "Cytochrome P4502C9: an enzyme of major importance in human drug metabolism," <i>J Clin Pharmacol</i> , 45:525-538 (1998)			
<i>W</i>	70	MORGAN et al., "Hypolipidemic, uricosuric, and thyroxine-displacing effects of MK-185 (halofenate)," <i>Clin. Pharmacol. Therap.</i> , 12:517-524 (1971)			
	71	NEUMAN, J. et al., <i>J. Cardiovasc. Surg. Torino</i> , Spec. No. 32-7-532-537			
<i>W</i>	72	PELKONEN, et al., "Inhibition and induction of human cytochrome P450 (CYP) enzymes," <i>Xenobiotica</i> , 28:1203-1253 (1998)			
<i>W</i>	73	RAVENSROFT, P.J. et al., <i>Clin. Pharmacol. Ther.</i> , 14:547-551 (1973)			
<i>W</i>	74	REAVEN, "Insulin Resistance and Human Disease: A Short History," <i>Journal of Basic & Clinical Physiology & Pharmacology</i> , 9:387-406 (1998)			
<i>W</i>	75	REAVEN, "Pathophysiology of Insulin Resistance in Human Disease," <i>Physiological Reviews</i> , 75:473-486 (1995)			
<i>O</i>	76	RYAN, "The metabolic spectrum of halofenate," <i>Int. J. Clin. Pharmacol.</i> , 12:239-243 (1975)			
<i>L</i>	77	SCHAPEL and EDWARDS, "Efficacy and Interactions of Oxandrolone, Halofenate and Clofibrate in a Factorial Study on Experimental Acute Nephrotic Hyperlipidemia," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 194:274-284 (1975)			
	78	SCHOLOSSSTEIN, L.H. et al., <i>J. Lab. Clin. Med.</i>, 82:412-418			
<i>W</i>	79	SIRTORI et al., "Clinical Evaluation of MK-185: A New Hypolipidemic Drug," <i>Lipids</i> , 7:96-99 (1971)			

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<i>A</i>	80	SKYLER, "Glucose Control in Type 2 Diabetes Mellitus," <i>Annals of Internal Medicine</i> , 127:837-838 (1997)		
<i>W</i>	81	STEINER et al., "A Comparative Review of the Adverse Effects of Treatments for Hyperlipidaemia," <i>Drug Safety</i> , 6:118-130 (1991)		
<i>W</i>	82	TASKINEN and SMITH, "Lipid disorders in NIDDM: implications for treatment," <i>Journal of Internal Medicine</i> , 244:361-370 (1998)		
<i>W</i>	83	<u>The University of Michigan Medical Center Journal, 36:247-248 (1970)</u>		
<i>W</i>	84	TRUST et al., "(Aryloxy)[p-(aryloxy)phenyl]- and (Aryloxy)[p-arylthio]phenyl]acetic Acids and Esters as Hypolipidemic Agents," <i>Journal of Medicinal Chemistry</i> , 22:1068-1074 (1979)		
<i>W</i>	85	TURNER and GLAPHAM, "Insulin resistance, impaired glucose tolerance and non-insulin-dependent diabetes: pathologic mechanisms and treatment: Current status and therapeutic possibilities," <i>Progress in Drug Research</i> , 51:34-94 (1998)		
<i>W</i>	86	VEDELL and PASSANANTI, "Differential Effects of Chronic Halofenate Administration on Drug Metabolism in Man," <i>Fed. Proc.</i> , 31:538 (1972)		
<i>W</i>	87	WILSON, J. et al., (ed.), "Disorders of Lipid Metabolism", Chapter 23 <i>Textbook of Endocrinology</i> , 9th Edition, W.B. Sanders Company, Philadelphia, PA U.S.A. (1998)		
<i>W</i>	88	WOLFRAM, G. et al., Verh. Dtsch. Ges. Inn. Med., 79:1291-1293 (1973)		
	89	WRIGHT, et al., "UKPDS 28: A Randomized Trial of Efficacy of Early Addition of Metformin in Sulfonylurea-Treated Type 2 Diabetes," <i>Diabetes Care</i> , 21:87-92 (1998)		

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